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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,894	07/17/2003	Georg Watzek	35931-PCT-USA-A 071986.02	1493

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,894	WATZEK ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/12/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

10

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, **claims 1-10 and 13**, in the reply filed on 7/25/2005 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The elected claims 1-10 and 13 are clearly directed to a product as written in these claims. Thus, the phrase that the elected claims 1-10 and 13 are drawn to a method for promoting bone tissue is considered to be a typing error (response page 2).

Claims 11, 12 and 14-16 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions of Group II (claims 11, 14 and 15) and of Group III (claims 12 and 16), there being no allowable generic or linking claim. Election was made without traverse.

Claims 1-10 and 13 are under examination in the instant office action.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 1/18/2001. It is noted, however, that applicant has not filed a certified copy of the A 89/2001 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

Claims 1-10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the use of microparticles derived from "tissues" in a drug composition. The nature of "tissues" is not pointed out as claimed. The "microparticles" are broadly defined in as-filed specification as blood cell fragments with cytoplasmic moieties (page 1, par. 1). No other source besides blood cells is disclosed. Thus, the scope of generic tissue(s) other than blood cells is broad beyond some reasonable limits since animal tissues contains millions of various "moieties" and compounds.

Claims 2-8 are indefinite because it is uncertain as claimed whether the claimed materials are additionally included into the drug composition or whether the claimed materials are the structural components of claimed "microparticles". The contents or components of "microparticles" are not disclosed in the as-filed specification.

Claim 13 is indefinite with respect to term "polyacton" because polymer with this name does not exist or, in alternative, the term is misspelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,165,938 (Kinghton).

Claims are directed to a drug composition for topical application as intended for wound healing wherein the composition comprises microparticles from blood cells, wherein

composition has been made under sterile conditions and subjected to virus inactivation and/or depletion and wherein composition is in a freeze-dried or deep-frozen state. Some claims are further drawn to the presence of growth factors or substances promoting wound healing in the drug composition. Some claims are further drawn to the presence of matrix materials, collagen, fibrinogen, thrombin and/or organic polymers and inorganic compounds in the drug composition. Some claims are further drawn to incorporation of biocompatible materials into the drug composition.

US 5,165,938 (Kinghton) discloses a drug composition produced from blood and intended for topical application and wound healing (abstract). The drug composition contains "microparticles" derived from platelet-rich plasma after activation and centrifugation. The "microparticles" are mixed with microcrystalline collagens and frozen (col. 2, lines 20-55 or col.3, lines 25-44). The drug composition is made under sterile condition (col.3, line 26). Blood is collected from normal patients that are not diagnosed with viral diseases and, thus, virus depleted or virus free. The cited patent discloses that drug composition contains growth factors PDAF and PDGF or substances promoting wound healing. Fibrinogen and thrombin are inherent components of a product derived from platelet rich plasma. Proteins and/or glycoproteins of platelet rich plasma fall within the meaning of generic organic polymers as claimed. The drug composition contains inorganic compounds or inorganic salts (col. 3, line 42). The cited patent teaches the use of composition in conjunction with biodegradable dressings and implantable devices (col. 4, lines 32-35).

Thus, the cited patent anticipates the claimed invention.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,185,160 (Chao).

Claims are directed to a drug composition for topical application as intended for wound healing wherein the composition comprises microparticles from blood cells, wherein composition has been made under sterile conditions and subjected to virus inactivation and/or depletion and wherein composition is in a freeze-dried or deep-frozen state. Some claims are further drawn to the presence of growth factors or substances promoting wound healing in the drug composition. Some claims are further drawn to the presence of matrix materials, fibrinogen, thrombin and/or organic polymers and inorganic compounds in the drug composition. Some claims are further drawn to incorporation of biocompatible materials into the drug

US 5,185,160 (Chao) discloses a pharmaceutical composition comprising viral-inactivated blood platelet membrane microparticles (abstract). Microparticles are derived from platelet poor plasma and separated by sequential centrifugations (col. 4, lines 1-60); virus inactivation is made by heat treatment (abstract and col. 4, lines 40-45); drug composition is provided in frozen or lyophilized (freeze-dried) state (col.4, lines 60-62); the drug composition is made under sterile conditions (col. 3, line 63). The drug composition comprises physiological saline (col. 4, line 41) and, thus, inorganic compounds. Fibrinogen and thrombin are inherent components of a product derived from plasma, particularly in view that the cited patent discloses that microparticles fractions retains "procoagulant" activity (col. 5, lines 64-67). Proteins and/or glycoproteins (GPIb, for example: col. 5, line 11) in the final preparation as disclosed fall within the meaning of generic organic polymers as claimed. Although the particular application of the cited product relates to transfusion as intended to reduce bleeding time, the bleeding reducing

drug would clearly be suitable in wound healing. The differences between drug composition as intended for transfusion and as intended for topical application would relate to carriers (inactive ingredient) or to dosage of active ingredient. The claimed invention is not so limited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,165,938 (Kinghton) and US 5,185,160 (Chao) taken with US 5,697,980 (Otani et al.).

Claims are directed to a drug composition for topical application as intended for wound healing wherein the composition comprises microparticles from blood cells, wherein composition has been made under sterile conditions and subjected to virus inactivation and/or depletion and wherein composition is in a freeze-dried or deep-frozen state. Some claims are further drawn to the presence of growth factors or substances promoting wound healing in the drug composition. Some claims are further drawn to the presence of matrix materials, collagen, fibrinogen, thrombin and/or organic polymers and inorganic compounds in the drug composition. Some claims are further drawn to incorporation of biocompatible materials into the drug composition.

Some claims are further drawn to biocompatible materials or carriers such as titanium, apatite and organic polymer "polyactone".

US 5,165,938 (Kinghton) and US 5,185,160 (Chao) are relied upon as explained above for the disclosure of drug comprising microparticles derived from blood platelets separated by centrifugation, subjected to viral inactivation, made under sterile conditions and provided in frozen and freeze-dried state. The cited drug compositions are intended for wound healing and reduction of bleeding. The cited drug compositions comprise carriers including collagen and saline as intended for particular mode of administration. US 5,165,938 (Kinghton) suggest incorporation of microparticles derived from blood platelets into dressing materials and as coating over implantable devices. But the cited patents are missing particular disclosure about the use of titanium, apatite and organic polymer "polyactone" as material for carriers and/or medical devices.

However, US 5,697,980 (Otani et al.) teaches artificial filling and prosthetic device(s) capable of adhering to tissues or to wounded tissues. The materials include titanium core coated with calcium phosphate (apatite) and organic polymers including polylactic acids, polycaprolactone, etc. For example: see abstract; col. 2, line 26 and lines 37-40; col. 3, lines 33-45 and col. 4, lines 10-17).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to add various carriers, fillings, biodegradable materials and devices including titanium, apatite and organic polymers modify to drug compositions with microparticles as suggested by US 5,165,938 (Kinghton) with a reasonable expectation of success in wound healing because the claimed carriers and materials are known and used for making artificial filling, carriers and medical devices as adequately demonstrated by US 5,697,980 (Otani et al.). One of skill in the art would have been motivated to adjust carrier

compositions of US 5,165,938 (Kinghton) and of US 5,185,160 (Chao) with regard to a mode of administration for the expected benefits in wound healing and bleeding reduction provided by microparticles derived from blood platelets.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571).272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

September 2, 2005

V. Afrem

VERA AFREMOVA

PRIMARY EXAMINER